Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1021288	(X3) Date Survey Completed 09/24/2025
Name of Provider or Supplier A2cl-Aurora Health Center Manitowoc County	**Street Address, City, State** 5300 Memorial Drive-Attn Lab Supervisor, Two Rivers, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records generated for submission to the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) program, patient records, and interview with a general supervisor (staff A), the laboratory did not perform testing on PT samples for electrolyte tests in the same manner as it tests patient samples for one of two general chemistry events completed to date in 2025. Findings include: 1. Review of laboratory records generated for general chemistry PT event one of 2025, revealed the laboratory had performed electrolyte testing on the PT samples on March 19, 2025, and repeated the tests on March 21, 2025, after completion of required instrument servicing due to an Integrated Multisensor Technology (IMT) measurement error. The laboratory reported the electrolyte results from March 21, 2025, to the WSLH PT program, after completion of instrument servicing. 2. Review of laboratory patient records revealed 61 patient samples had electrolyte testing performed and resulted between March 19, 2025, and March 20, 2025. 3. Interview with staff A on September 24, 2025, at 10:45 AM, confirmed the laboratory repeated PT sample testing for electrolytes after servicing was performed on the instrument and submitted the repeated results to the PT program, but continued

	to perform and report electrolytes for patients during the same period of time, confirming the laboratory did not test PT samples in the same manner as it tests patient samples.
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor review of documented humidity readings in the laboratory and interview with a general supervisor (staff A), the laboratory director did not ensure the humidity in the laboratory was appropriate for the testing performed on the Sysmex XN-450 and Dimension Xpand Plus analyzers for 21 out of 31 days in December 2024. Findings include: 1. Review of the "Monthly Report" for the "Manit MOB Humidity" sensor from the laboratory's continuous temperature monitoring system, SensoScientific, revealed the average relative humidity reading was less than 20% for 21 out of 31 days in December 2024. 2. Review of the performance specifications for the Sysmex XN-450 and Dimension Xpand Plus revealed the relative humidity requirements were 20-85% and 20-80%, respectively. 3. Interview with staff A on September 24, 2025, at 2:00 PM, confirmed the relative humidity readings seen on the SensoScientific report were outside the relative humidity requirements for the Sysmex XN-450 and Dimension Xpand Plus analyzers, and that the laboratory director did not ensure the laboratory could maintain appropriate humidity levels as defined by the analyzers' manufacturers during patient testing.